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PAPER

Applying statistical process control to monitor and evaluate the hazard analysis critical control point hygiene data

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Rapid hygiene testing systems employing the ATP Bioluminescence Technique are widely used to assess the hygiene status of various Control Points (CPs) in any Hazard Analysis Critical Control Point (HACCP) system. The measurement in Relative Light Units (RLU) is then used to give a Pass/Fail status to the CP tested. This paper highlights the potential benefits of applying appropriate Statistical Process Control (SPC) tools like Cusum Charts and Individuals Charts to the RLU data. In a typical dairy operation, RLU data collected over a period of three months from a CP of a milk filling machine were analysed in retrospect. The analysis showed that the Cusum and Individuals Charts established a proper trend analysis of the RLU data. Advance warning signs signifying potential out of control (Fail) CP status were clearly shown on the charts. The findings highlight the fact that by employing SPC, it is possible to prevent CPs from failing the hygiene test. Furthermore, if the SPC technique of identifying assignable and unassignable causes of failure was adopted, the total number of failed CPs should decrease. This would, in the long run, lead to more effective hygiene management and more efficient production. © 1997 Elsevier Science Ltd.

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INTRODUCTION

Rapid hygiene testing systems based on the measurement of adenosine triphosphate (ATP), i.e. ATP Bioluminescence Technique, provide an invaluable contribution to the Hazard Analysis Critical Control Point (HACCP) approach to food safety, as such testing systems can give microbial (and non-microbial) real time data of the Control Point (CP) tested. The reading, in the form of number of Relative Light Units (RLU), is then used to assess the hygiene status of the CP by comparing with a maximum, tolerable RLU reading (obtained through previous evaluation tests), resulting in a Pass/Fail status for the CP tested.

Although useful in preventing a failed CP from operation, this method of operating the rapid hygiene

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testing system gives no proper trend analysis nor advance warning as to when a CP is having a high probability of being out of control. The purpose of this study was to establish a trend analysis of the RLU data by treating the data with appropriate Statistical Process Control (SPC) tools to monitor and evaluate the CPs statistically, in order to obtain advance warning on the status of a CP and not just a Pass/Fail classification.

In order to make sure that the SPC charts employed in this study are suitable for the process, a process capability study should first be carried out to establish that the process is in control. For this study the process capability index (C_{pk}) value was found to be 1.35 indicating that the process was in control. In addition, at this stage, assignable causes of faults should be eliminated where possible. (However, as this study used historical data, this cannot be done.)

METHODS

The RLU data used for this study were obtained from a local dairy. The CP in question was the Mandrel of a milk filling machine and it was tested every day before production. Data were collected over a period of three months and analysed in order to establish a reasonable trend analysis.

Traditional Control Charts are not suitable tools for analysis of the RLU data as the data were all single measurements (sample size, $n = 1$). Under such circumstances, Cusum Charts are suitable alternatives (Newton, 1994). Another suitable SPC tool is the Individuals Chart (Oakland, 1996).

Both sorts of chart are constructed and interpreted assuming that the observations follow, at least approximately, a normal distribution. This assumption is even more critical when the observations consist of single measurements, as in this case. Simple exploratory analyses of the data suggest that the assumption of normality may not be reasonable, in this case, and plots based on the raw data should be interpreted with some caution. A more realistic assumption for this set of data is probably that the observations of the RLUs follow a Poisson process. Quality Control procedures for dealing with such data often suggest modifications to the basic construction of the plots in terms of calculating action and warning limits. However, a more general method is to consider a transformation of the original data so that they more closely follow a normal distribution (Box and Cox, 1964; Atkinson, 1985) and, given this, plots can be constructed and interpreted in the conventional manner. The usual method of transforming Poisson distributed data to achieve normality is to take square roots. Again, exploratory data analysis suggests that, in this case, the transformed data are approximately normally distributed. The main effect of the transformation is to reduce the overall noise in the observations so that, in some cases, actions for the untransformed data are reduced to warnings for the transformed data, although the overall interpretation of the plots remains the same.

The RLU data were analysed using Minitab Version 9.2.

RESULTS

The RLU data from the Mandrel CP over a period of three months are shown in *Table 1.*

Of the 92 measurements, only Day 74 was classified as a Fail since an RLU reading of 319 exceeded the pre-evaluated maximum RLU reading of 250.

The untreated data gave no indication that Day 74 would be out of control. In fact, by examining the untreated data, a confusing picture emerged: Day 69, 70 and 71 were all of high RLU readings whereas Day 72 and 73 had RLU readings nearly half of the previous three days' readings and then Day 74 became a Fail classification.

The statistically treated data are shown in *Figures 1* (Cusum Chart) and *2* (Individuals Chart) and they gave a very different picture.

Referring to *Figure 1* and by placing the V-mask on Day 70, a warning signal appeared. Warning signals also appeared on Day 51, 70, 71 and 73 (*Figure 2*). The numbers on the chart represent the test number of the eight tests for special causes (which detect specific patterns in the data plotted on the chart) by the Minitab programme. For example, the number 6 for Day 51 refers to pattern 6 which is four out of five points in a row in zone B or beyond, where zone B contains the area between the 1- and 2-sigma limits from the centre line. For further details, please refer to the article by Nelson (1984).

Both charts thus gave clear advance warnings that Day 74 could well be out of control. In other words,

Table 1

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
RLU	23	46	39	62	33	21	20	56	69	26	27	24	22	69	42	97	56	33	33	69	24	34	29	29	19	57	81	99
DAY	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56
RLU	43	80	68	112	25	52	24	35	15	47	104	53	81	34	17	62	23	123	147	13	12	15	14	76	28	29	44	15
DAY	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84
RLU	16	123	5	41	56	9	82	22	22	63	85	34	158	164	155	79	94	319	38	19	64	50	16	25	28	35	52	28
DAY	85	86	87	88	89	90	91	92																				
RLU	35	52	139	89	62	55	12	67																				

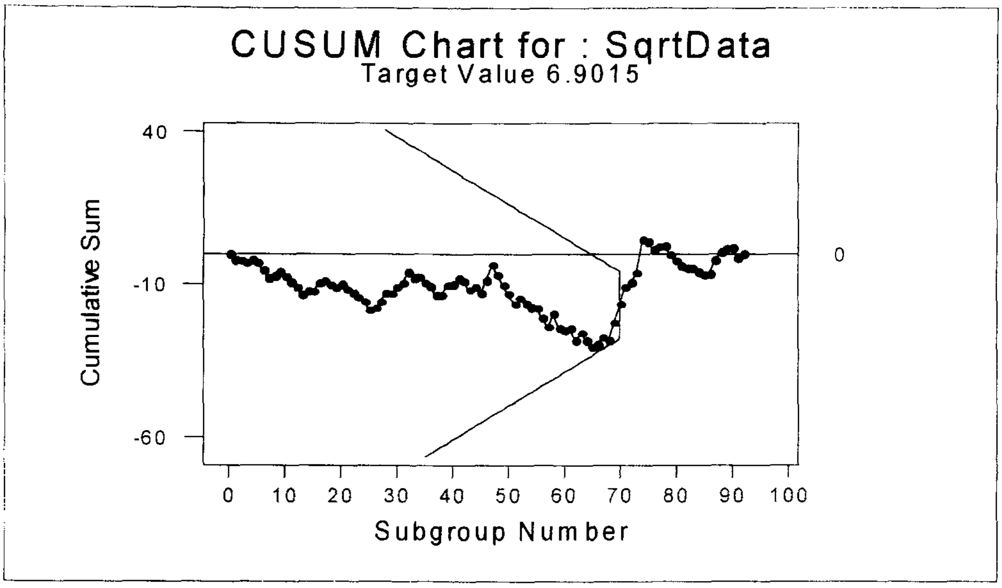

Figure 1 Cusum Chart for transformed data

the out of control (Fail) situation on Day 74 could have been prevented had some necessary corrective actions been taken during Day 73 or earlier.

DISCUSSION

The fundamental philosophy behind the HACCP system is one of PREVENTION and the same is true of SPC. Integrating SPC with the HACCP system would further enhance this prevention philosophy as on this occasion by way of a proper trend analysis.

In this study, the trend analysis was done in retrospect. It was impossible to locate the cause(s) for the Fail classification of Day 74. However, given a real-time situation, investigations should have been carried out as early as Day 51 to identify possible causes of high RLU readings (assignable and unassignable). Assignable causes in this example could be: contamination of swabs, errors in setting up the hygiene test, reading errors of the RLU metre...etc. Unassignable causes could be: wear and tear of the Clean-In-Place disinfection system, gradual build-up of dirt over the three months period...etc. By continuously eliminating the possible causes of failure, the number of failed CPs should decrease.

The major drawback associated with the monitoring and control of food processes by means of traditional microbiological analysis, has been the time delay. Invariably, the products were on the supermarket shelf before the analysis had been completed. SPC techniques bring about real-time control of food operations and provide management with advanced warnings of hazards or non-conformance. The bene-

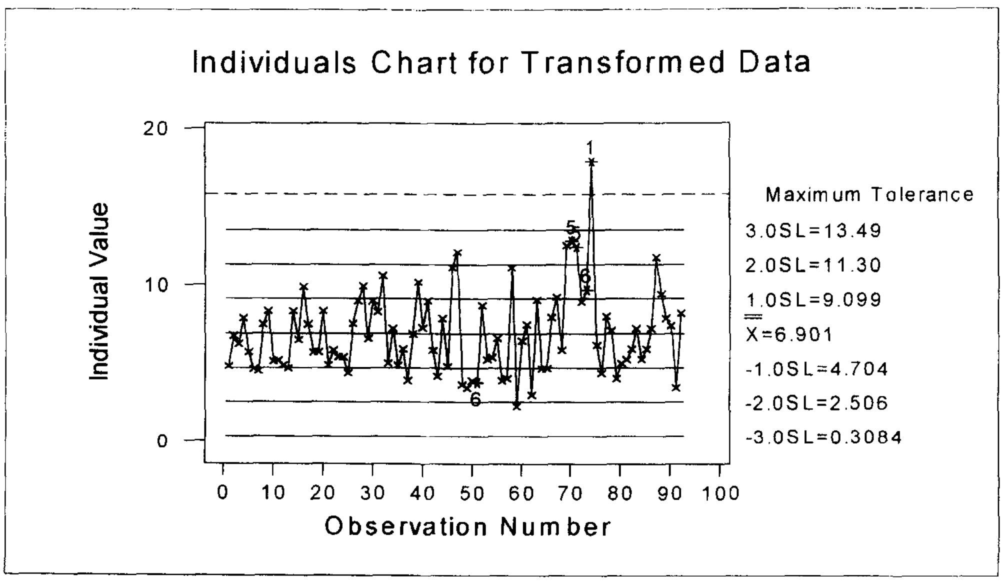

Figure 2 Individuals Chart for transformed data

fits of such a powerful control tool to the consumers, in terms of food safety, cannot be over-emphasised.

As the main aim of this study was to demonstrate the potential benefits of applying SPC to the HACCP hygiene data, it is recommended that further studies should be carried out in real-time situations, in order to fully evaluate the benefits.

CONCLUSION

By applying suitable SPC tools, e.g. Cusum Charts and Individuals Charts to the RLU hygiene data from one of the CPs of a HACCP system, proper trend analysis can be obtained. Instead of just a Pass or Fail classification for the CP tested, advance warnings will also appear on the charts, so that with appropriate corrective actions, failures can be prevented. SPC can contribute greatly towards a more effective HACCP hygiene management system and bring about a more efficient production in the long term.

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